

No. 1:17-MD-2804

United States District Court
Northern District of Ohio

In re: National Prescription Opiate Litigation

**BRIEF OF *AMICI CURIAE* IN SUPPORT OF A SETTLEMENT
AGREEMENT INCLUDING BROAD TRANSPARENCY
PROVISIONS IN THE INTEREST OF FUTURE RESEARCH**

Brief of *Amici Curiae*

American Medicine and Public Health Historians and
the Organization of American Historians

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TABLE OF AUTHORITIES

CASES

Brown & Williamson Tobacco Corp. v. Regents of the Univ. of Cal., C.A. No. 967298 (Cal. Sup. Ct. May 25, 1995), available at https://www.industrydocuments.ucsf.edu/wp-content/uploads/2014/10/bw_ucregents.pdf 9

Cipollone v. Liggett, 822 F.2d 335 (3d Cir. 1987)

Commonwealth of Kentucky v. Purdue Pharma L.P., Case No. 07-CI-01303 (Pike Cir.)

State of Oklahoma v. Purdue Pharma L.P. et al., Case No. CJ-2017-816 (Clev. Cty. Dist. Ct.)

United States v. Philip Morris, USA Inc. et al., 449 F. Supp. 2d (D. D.C. 2006)

OTHER AUTHORITIES

1998 Master Settlement Agreement.

ALLAN M. BRANDT, *THE CIGARETTE CENTURY: THE RISE, FALL, AND DEADLY PERSISTENCE OF THE PRODUCT THAT DEFINED AMERICA* (2007).

Brief of Amici Curiae in Support of Settlement with Favorable Public Health Outcomes, In re: Nat'l Prescription Opiate Litig., MDL No. 2804 (May 9, 2019) [Dkt #1607-1]

Anne Case & Angus Deaton, *Rising Morbidity and Mortality Rates in Midlife among White Non-Hispanic Americans in the Twenty-First Century*, 112(49) PROC. NAT'L ACAD. SCI. U.S. 15078 (2015).

Caroline Lilyard, *The Minnesota Tobacco Trial, 1994-1998*, 28(1) REF. SERV. REV. 8 (2000).

ELIZABETH C. BURCH, *MASS TORT DEALS: BACKROOM BARGAINING IN MULTIDISTRICT LITIGATION* (2019).

GERALD MARKOWITZ & DAVID ROSNER, *DECEIT AND DENIAL: THE DEADLY POLITICS OF INDUSTRIAL POLLUTION* (2002).

GERALD MARKOWITZ & DAVID ROSNER, *LEAD WARS: THE POLITICS OF SCIENCE AND THE FATE OF AMERICA'S CHILDREN* (2013).

INDUSTRY DOCUMENTS LIBRARY, *Bibliography: Publications Based on Truth Tobacco Industry Documents*

Jennifer D. Oliva, <i>Opioid Multidistrict Litigation Secrecy</i> , 80 OHIO ST. L. J. __ (forthcoming 2019), available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3411746 & download=yes.....	18
Lisa Bero, <i>Implications of the Tobacco Industry Documents for Public Health and Policy</i> , 24 ANN. REV. PUB. HEALTH 267 (2003).....	12
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Stanton Glantz, <i>Lawsuits Against Companies Aren't Just About Getting Money. They're About Revealing the Truth</i> , THE WASHINGTON POST (Sept. 9, 2019), https://beta.washingtonpost.com/opinions/2019/09/09/lawsuits-against-companies-arent-just-about-getting-money-theyre-about-revealing-truth/?outputType=amp	9
Stanton Glantz et al., <i>Looking Through a Keyhole at the Tobacco Industry: The Brown and Williamson Documents</i> , 274(3) JAMA 219 (1995).....	9

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

IN RE: NATIONAL PRESCRIPTION)	MDL No. 2804
OPIATE LITIGATION)	
)	Case No. 1:17 MD 2804
)	
THIS DOCUMENT RELATES TO:)	Judge Dan Aaron Polster
)	
ALL CASES)	
_____)	

**BRIEF OF *AMICI CURIAE*
IN SUPPORT OF A SETTLEMENT AGREEMENT INCLUDING BROAD
TRANSPARENCY PROVISIONS IN THE INTEREST OF FUTURE RESEARCH**

INTERESTS OF *AMICI CURIAE*

The *amici curiae* are 35 historians of American medicine and public health and the Organization of American Historians (OAH). *Amici* have no direct stake in the outcome of the settlement negotiations, nor does our brief take a position in the bellwether cases or on the overall scope and structure of a potential settlement. Instead, we come before the court to express our belief in the need for sustained research in all dimensions—medical, economic, social, and cultural—of the prescription opiate crisis. *Amici* contend that, through the inclusion of such transparency provisions as are described in the present brief, a settlement has the potential to secure the conditions for impactful research into the origins and ramifications of this defining crisis in the recent history of our nation.

Individual signatories are faculty members at leading research universities with distinguished publication records on such topics as the history of drugs, drug addiction, and drug policy; racial and socio-economic disparities in U.S. health care; corporate influence in the

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*** Disclosure: Dr. Podolsky is a member of the UCSF Center for Tobacco Control Research and Education's External Advisory Committee. The Center for Tobacco Control Research and Education was established in parallel with the UCSF Industry Documents Library, which forms the subject of this brief. Both programs are located on the same premises and have collaborated on tobacco-related research and education projects in the past. However, they are institutionally separate and rely on different sources of funding.

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The **Organization of American Historians** (OAH), established in 1907, is the largest professional society dedicated to the teaching and study of American History. It currently represents more than 7,800 historians working in the U.S. and abroad. Its membership consists of college and university professors, precollegiate teachers, archivists, museum curators, public historians, students, and a variety of scholars employed in government and the private sector. Its core missions include the promotion of open access to historical resources and scholarship, the exhibition and preservation of artifacts, the discussion of historical questions, and the dissemination of knowledge.

The views of individual signatories as expressed in this brief do not necessarily represent the views of any university or other institutions. Moreover, the views expressed in the brief do not necessarily represent the views of any individual members or other institutions affiliated with the Organization of American Historians.

ARGUMENT

Addiction is in some respects an intensely individual experience; it grows out of uniquely personal histories and often severs the bonds that tie a victim to potential communities of support. At the same time, every victim of the opioid epidemic in America was caught in a web of circumstances that stretched far beyond the grasp of individuals and individual communities. The list of these circumstances is a long one; it includes the potency of the drugs themselves, the power of marketing methods honed over decades by a resourceful and ill-regulated industry, an imperfect and inequitable health care system, a lack of adequate treatments for patients living with chronic pain, and a prevailing culture that views substance abuse through a moral rather than medical lens. These interlocking factors produced their most devastating effect in places where deepening economic insecurity made people vulnerable to what a landmark study on the subject termed “deaths of despair.”¹ The scope of the resulting crisis is such that no settlement, no matter the amount of damages, can aspire to repair all of the harm done, if only because so much of the loss incurred is of the kind that cannot be repaid or repaired.

Nonetheless, *amici* believe in the possibility of a successful settlement that could serve several critical interests of the public. Among these interests is access to information. The concealment of information about the abuse potential and distribution patterns of opioid painkillers allowed the opioid crisis to take root in the first place and to grow to its current dimensions. Since secrecy fueled the crisis, no just and genuinely remedial settlement can be reached unless it honors the public’s right to know and secures the conditions for its effective exercise into the future. As scholars, *amici* regard it as their mission to bring to light the largely hidden web of social and economic forces, corporate practices, cultural beliefs, and political

¹ Anne Case and Angus Deaton, *Rising Morbidity and Mortality Rates in Midlife among White Non-Hispanic Americans in the Twenty-First Century*, 112(49) PROC. NAT’L ACAD. SCI. U.S. 15078 (2015).

decisions in which the victims of the crisis were trapped. While *amici* welcomed this Court's recent decisions to unseal illuminating documents obtained in discovery in the above-captioned matter, they also believe that a prospective settlement should take additional steps to guarantee full and permanent access to the records that will enable scholars and policymakers to develop evidence-based measures aimed at remedying the crisis in future years. A settlement exclusive of such provisions, *amici* fear, might entail yet another irreparable loss.

In this regard, the parallels between the tobacco and opioid litigation hold valuable lessons. In both cases, the profits accumulated by the defendants in selling an addictive product, however considerable, were dwarfed in the end by the resulting medical costs and loss of productivity—not to mention the loss of life and limb. This means that in the case of tobacco no more than in that of opioids there could be a realistic hope of devising a settlement that compensated all victims and met all legitimate expectations. On the specific issue of access to information, however, there is a broad consensus that the 1998 tobacco Master Settlement Agreement (MSA) between the major U.S. cigarette manufacturers and the States succeeded beyond expectations. In what follows, then, *amici* outline the MSA's key transparency provisions, highlight their implications for tobacco-related research and policymaking, and argue that any settlement agreement in the instant MDL should include provisions drawn along the same lines.

I. THE TOBACCO INDUSTRY DOCUMENTS: A MODEL FOR THE PRESENT CASE

A. *Historical Introduction: The Public's Right to Know in the Tobacco Litigation*

An initial trove of secret tobacco industry documents collected by a whistleblower from the Brown and Williamson Tobacco Corporation (B&W) reached the Attorney General of the State of Mississippi, Congress, and the press in early 1994.² One set of these documents was also forwarded to Professor Stanton Glantz, a renowned specialist on the health hazards of tobacco smoke at the University of California, San Francisco (UCSF). Dr. Glantz deposited the documents at the UCSF Library so they would become available to other researchers.³ Despite the comparatively limited number of pages involved, these documents turned out to be of considerable significance for subsequent efforts to expose the internal workings of the tobacco industry. B&W filed suit against the University of California in an unsuccessful effort to recover them.⁴ Invoking the “very strong public interest” in “permitting this information to remain for use by the University or by others who may obtain it from the University,” the court ruled against the company, allowing UCSF to place the documents on the Internet as early as June 1995.⁵

The B&W papers provided some of the clearest and most publicized evidence to date that the tobacco industry had known about the addictive properties of nicotine at least as far back as the 1960s and had deliberately withheld that knowledge from the public. Within months of their

² ALLAN M. BRANDT, *THE CIGARETTE CENTURY: THE RISE, FALL, AND DEADLY PERSISTENCE OF THE PRODUCT THAT DEFINED AMERICA* at 369-375 (2007).

³ See Stanton Glantz et al., *Looking Through a Keyhole at the Tobacco Industry: The Brown and Williamson Documents*, 274(3) JAMA 219 (1995). See also the account recently provided in Stanton Glantz, *Lawsuits Against Companies Aren't Just About Getting Money. They're About Revealing the Truth*, THE WASHINGTON POST (Sept. 9, 2019).

⁴ *Brown & Williamson Tobacco Corp. v. Regents of the Univ. of Cal.*, Case No. 967298 (Cal. Supr. Ct. May 25, 1995), available at https://www.industrydocuments.ucsf.edu/wp-content/uploads/2014/10/bw_ucregents.pdf.

⁵ *Id.* The public's right to access discovery documents produced in public interest litigation had been the subject of protracted arguments in a prior cigarette tort case: *Cipollone v. Liggett*, 822 F.2d 335 (3d Cir. 1987).

disclosure, State Attorneys General across the nation initiated the civil lawsuits against tobacco manufacturers that ended in the signing of the Master Settlement Agreement four years later. In the intervening years, three states—Mississippi, Texas, and Florida—settled separately with the tobacco companies. In Minnesota, the case proceeded to trial. During the most far-reaching discovery process ever to be conducted in the tobacco litigation, lawyers for the State obtained more than thirty million pages of memoranda, reports, meeting minutes, letters, and other confidential company records. They also produced extensive evidence of industry maneuvers to destroy or conceal incriminating materials, including through sweeping assertions of attorney-client privilege. On May 8, 1998, hours before jury deliberations were set to begin, the tobacco defendants agreed to a settlement in the amount of \$6.6 billion. In addition, the settlement agreement compelled the defendants to maintain for a period of ten years two separate depositories in which the millions of once-secret documents uncovered during the proceedings were to be put at the public’s disposal.⁶

B. The MSA’s Transparency Provisions

The MSA, executed six months after the Minnesota settlement, further expanded access to internal tobacco industry documents through a combination of two sets of provisions:

(1) Public Access to Documents (MSA Section IV)

MSA Sections IV(a) and IV(b) compelled the participating tobacco manufacturers to support an application for the dissolution of all protective orders on the documents produced in the course of the state lawsuits. Exceptions were provided solely for such documents as to which the defendants had made successful claims of privilege, trade-secret protection, or confidential or

⁶ BRANDT, *supra* note 2, at 415-419; Caroline Lilyard, *The Minnesota Tobacco Trial, 1994-1998*, 28(1) REF. SERV. REV. 8, 11-14 (2000).

proprietary business protection, and for documents whose disclosure would cause harm to personal privacy interests or the contractual rights of third parties.

MSA Section IV(c) also required each participating manufacturer to maintain, for a period of twelve years and at its own expense, a website on which all documents released under the terms of MSA Section IV were to be posted. Said documents included those produced to the settling states during the pendency of the proceedings settled by the MSA as well as other documents produced or listed as trial exhibits in a number of prior cases.⁷

(2) Establishment of a National Foundation (MSA Section VI)

MSA Section VI further provided for the establishment of an independent foundation dedicated to educating the public on the risks of tobacco use. That foundation, known as the American Legacy Foundation (until it was renamed Truth Initiative in 2015), in turn funded the creation of the Legacy Tobacco Documents Library at UCSF, where the B&W papers had been held since 1995. When it was unveiled in 2002, the online Legacy Library contained twenty-four million pages of documents that the industry had turned over to the National Association of Attorneys General (NAAG) subsequent to the execution of the MSA. In following years, the Library downloaded millions of additional items from the document websites that participating manufacturers were required to maintain pursuant to MSA Section IV(c) in order to index and upload them onto its own specially-designed web portal.⁸

⁷ MSA Section IV(d) & Exhibit H, “Document Production.” The list included, among other matters, the Mississippi, Texas, Florida, and Minnesota suits that had been settled prior to the execution of the MSA as well as an extensive list of FTC investigations into the tobacco industry’s advertising practices.

⁸ The gift from the Legacy Foundation to the UCSF Library was in the amount of \$12.5 million: a \$2.5 million fund for initial expenses including staffing and infrastructure costs and a \$10 million fund to serve as an endowment to support maintenance and preservation of the collections in perpetuity. The project claimed only a minimal fraction of the \$1.7 billion that the MSA had committed to supporting the Foundation’s missions.

C. The Industry Documents Library (IDL) and its Significance for Research

The creation of the Legacy Tobacco Documents Library provided the impetus for a new wave of scholarship on what is still, by many measures, the worst man-made public health catastrophe in U.S. history. Before the Library went live in 2002, the tobacco industry documents remained scattered across multiple physical and digital depositories. The sheer volume of the documents produced by the tobacco litigation represented another daunting challenge for researchers. The industry had neither the expertise nor the interest to sort, process, and catalogue millions of documents in the interest of future research. It took the work of a dedicated team of skilled digital librarians to transform what were in effect massive “document dumps,” both paper and digital, into a single, permanent, and easily searchable online archive. Every document posted on the Library’s website is described in an extensive set of metadata (*e.g.* title, author, date, provenance, type of document, length) that guarantees its retrievability; and the content of every text document is itself rendered fully text-searchable through optical character recognition (OCR) software.⁹

Hence, the Legacy Library emerged as a resource of unmatched depth and richness for historians of science, medicine, and technology as well as historians of American business, marketing, and consumer cultures. A bibliography maintained on the Library’s website currently lists in excess of one thousand references to books, scientific or scholarly journal articles, policy papers, and newspaper reports based on documents in its collections. It is no exaggeration to state that, thanks to the Legacy Library, we know more about the tobacco industry and its

⁹ See Lisa Bero, *Implications of the Tobacco Industry Documents for Public Health and Policy*, 24 ANN. REV. PUB. HEALTH 267 (2003), on the challenges of exploiting the tobacco industry documents prior to the Legacy Tobacco Documents Library’s creation; and ROBERT N. PROCTOR, *GOLDEN HOLOCAUST: ORIGINS OF THE CIGARETTE CATASTROPHE AND THE CASE FOR ABOLITION* at 15-6 (2011), on the transformative potential of fully searchable digital archives for historical research.

internal workings than any other modern industry.¹⁰ Nor is the significance of the Library's documentary holdings confined to the history of tobacco. Two prominent historians of science, for example, relied on them to trace the origins of strategies recently employed by the fossil fuel industry to challenge the scientific consensus on climate change to strategies first devised by the tobacco industry to mislead the public on the link between tobacco smoke and lung cancer.¹¹ Given Big Tobacco's pioneering role in the development of marketing, public relations, and legal strategies designed to deceive the public, forestall regulation, and escape accountability in court, the tobacco documents shine an exceptionally bright light on corporate practices now adopted across regulated industries to undermine legally mandated oversight.

To facilitate cross-industry investigations of corporate practices influencing public and environmental health, the Legacy Library eventually expanded its mission beyond the collection of tobacco documents. In 2006, it established the Drug Industry Documents Archive (DIDA) as a companion site to the Tobacco Documents Library. More recently, additional sections were created to make chemical, food, and fossil fuel industry documents available through the same interface as the tobacco and pharmaceutical industry documents. These various collections are all freely accessible to researchers and the public through a single web portal renamed Industry Documents Library (IDL) in 2015. With over 91 million pages of documents as of the filing of this brief, IDL is the largest business archive in the world, and one that sets global standards for accessibility, ease of use, and impact.¹²

¹⁰ *Bibliography: Publications Based on Truth Tobacco Industry Documents*, INDUSTRY DOCUMENTS LIBRARY, https://industrydocuments.ucsf.edu/tobacco/biblio/#q=%3A*&subsite=tobacco&cache=true&count=1004 (last visited Sept. 9, 2019).

¹¹ NAOMI ORESKES & ERIK CONWAY, *MERCHANTS OF DOUBT: HOW A HANDFUL OF SCIENTISTS OBSCURED THE TRUTH ON ISSUES FROM TOBACCO SMOKE TO GLOBAL WARMING* (2010).

¹² *See Overview*, INDUSTRY DOCUMENTS LIBRARY, <https://www.industrydocuments.ucsf.edu/about/overview/> (last visited Sep. 5, 2019).

II. A PLEA FOR TRANSPARENCY PROVISIONS IN A SETTLEMENT OF THE OPIOID LITIGATION

A. Three Essential Conditions

As the history of the tobacco documents makes plain, the unsealing of industry litigation documents is merely a first step in the effort to make them genuinely accessible to researchers and the public. In order to maximize the benefits of a disclosure of the opioid manufacturers' and distributors' internal documents, the following conditions must be met as well:

(1) The Documents Should be Accessible through a Single Web Portal

In hindsight, there is little doubt that the impact of the millions of industry documents disclosed in the course of the tobacco litigation would have been greatly reduced had they remained dispersed across courthouses, brick-and-mortar depositories, corporate archives, and/or temporary company websites. The cost of assembling the documentary base for any comprehensive research project on the history of tobacco would have remained prohibitively high, and the research output correspondingly low. Critical research findings would have been slower to emerge; their tentative nature would have cast a lasting shadow on their value and public reception.

Fortunately, the tobacco documents escaped this fate. The transfer of tobacco litigation documents onto a single digital platform consultable at no cost to anyone with an Internet connection created genuine accessibility for researchers as well as for numerous constituencies beyond the academic research community. Indeed, IDL documents have been used in multiple court proceedings and congressional hearings.¹³ They have been studied and cited by journalists,

¹³ The IDL documents were cited extensively, for example, in the United States Department of Justice's action against the leading American cigarette manufacturers under the federal Racketeer Influenced and Corrupt Organizations (RICO) Act. *See, e.g.,* United States' Final Proposed Findings of Fact, *United States v. Philip Morris*, 99-CV-02496 (D. D.C. Jul. 1, 2004) [Dkt #3443]. The final judgment in that case further expanded the range of documents that tobacco companies were compelled to disclose as well as extended the duration of time that the

teachers, and students. And perhaps most important insofar as justice is concerned, the truths they hold are within the reach of each and every victim whose right to know what the tobacco industry knew, concealed, and even denied for decades is now beyond dispute.

(2) The Documents Should be Processed at Defendants' Expense

Given the sheer volume of evidence likely to be produced in the course of the opioid litigation, bringing the released documents into a unified archiving and indexing scheme is of the essence. It is the only way to rescue researchers from the needle-in-a-haystack problem that stymied any effort to exploit the tobacco industry documents prior to the creation of the Legacy Library. In order to make it retrievable and exploitable at a later date, every document ought to be processed and indexed prior to its release. This work ought to be undertaken by skilled digital archivists, and has a cost which the defendants have the wherewithal and, *amici* contend, the responsibility to shoulder.

(3) The Documents Should be Maintained in a Stable Digital Environment

Research takes time, all the more so when the evidence that demands study is as voluminous and complex as it is in the matter at hand. The first comprehensive and fully documented accounts of the history of the tobacco catastrophe, for instance, appeared in the last ten to fifteen years—that is, whole decades after the peak of U.S. tobacco consumption and the first consequential efforts to bring tobacco manufacturers to account, but in relatively short order upon the creation of the Legacy Library.¹⁴

companies were required to maintain the documents on their respective internet document websites. *See* Final Judgment and Remedial Order, *United States v. Philip Morris*, 99-CV-02496 (D. D.C. 2006), at 10-16, available at https://www.justice.gov/sites/default/files/civil/legacy/2014/09/11/ORDER_FINAL_0.pdf.

¹⁴ *E.g.* BRANDT, *supra* note 2; PROCTOR, *supra* note 8; and SARAH MILOV, *THE CIGARETTE: A POLITICAL HISTORY* (forthcoming 2019). The same is true of influential scholarship on other large-scale public health catastrophes such as lead poisoning. *See* GERALD MARKOWITZ & DAVID ROSNER, *DECEIT AND DENIAL: THE DEADLY POLITICS OF INDUSTRIAL POLLUTION* (2002) and GERALD MARKOWITZ & DAVID ROSNER, *LEAD WARS: THE POLITICS OF SCIENCE AND THE FATE OF AMERICA'S CHILDREN* (2013), which relied in part on industry documents released in the course of litigation against lead paint manufacturers.

Likewise, research on the opioid crisis remains in its infancy and should continue to grow in scope and depth beyond the present generation of scholars. Therefore, it is critical that any settlement agreement ensure that the documents disclosed in the current litigation are permanently accessible and preserved in a stable environment such that they can be retrieved and referenced for as long as interest into the opioid crisis is likely to endure. In fact, *amici* submit that a settlement in the instant litigation ought to go farther than the MSA, which only guaranteed access to industry documents until 2010, by providing for the preservation of the opioid litigation documents into perpetuity.¹⁵

B. Amici's Proposal

Accordingly, we submit that any settlement in the above-captioned prescription opiate litigation should:

(1) Incorporate, *mutatis mutandis*, sections IV(a) and IV(b) of the MSA, which secured the removal of protective orders and/or seals on all documents produced in the litigation as to which participating manufacturers had no *bona fide* confidentiality claim;

(2) Order that the settling defendants make such documents available to the entity established to oversee the settlement's execution and supply the funding needed to index, publicize, and maintain those documents on a durably established and freely accessible digital archive designated by said entity for these purposes.

If the settlement were to provide for the creation of a public-interest foundation following the model of the American Legacy Foundation (now Truth Initiative), *amici* respectfully recommend that the settlement vest that foundation with the authority to determine how and where the funds and documents should be directed so as to best fulfill the three above-

¹⁵ Absent the Truth Initiative's decision to support the transfer of the tobacco documents to IDL and the Final Judgment and Order in *United States v. Philip Morris*, *supra* note 13, those invaluable public resources may well have been lost by now.

enumerated conditions. *Amici* further submit that several signatories to this brief would be well-qualified to advise the settlement administrators in this matter.

These two recommendations are to some degree independent. Thus, *amici* maintain that, no matter the eventual scope of discovery materials unsealed in the course of these or related litigation matters, the settling defendants should provide the funds for their collection, cataloguing, and preservation in the public interest.¹⁶

C. Funding Requirements

For the purpose of assisting this Honorable Court, *amici* have appended a proposal cost estimate prepared by UCSF's Industry Documents Library to this brief. According to this estimate, funding in the amount of \$30 million, which includes \$5 million for initial expenses and \$25 million to serve as an endowment, would enable the Library to acquire, index, post, and maintain as many as seven million opioid documents (twenty-eight million pages) on its website in perpetuity.¹⁷ *Amici* understand that there may be reasons unknown to them that counsel in favor of establishing an opioid litigation document archive under different institutional auspices. While IDL's record offers the highest level of guarantees, *amici* acknowledge, as they must, that the goals outlined in this brief could be achieved in a different institutional context.

CONCLUSION: ON THE IMPORTANCE OF INDUSTRY DOCUMENTS FOR PUBLIC HEALTH REFORM

The chief purpose of ensuring public access to the documents disclosed in the above-captioned proceedings is not to satisfy the curiosity of a narrow circle of academic researchers,

¹⁶ Related litigation matters would typically include the suits filed against defendant manufacturers and distributors by State Attorneys General in state court. The documents unsealed in those cases—most recently in *Kentucky ex rel. Conway v. Purdue Pharma L.P. et al.*, Case No. 07-CI-01303 (Pike Cir.), following a 2016 motion to unseal records by the Boston Globe—or added to parties' trial exhibit lists in *Oklahoma ex rel. Hunter v. Purdue Pharma L.P. et al.*, Case No. CJ-2017-816 (Cleveland Cty. Dist. Ct.), should be included in the list of documents to be collected and preserved at the settling defendants' expense.

¹⁷ These two numbers are unofficial estimates provided to IDL by a source with knowledge of the Massachusetts opioid case. At this stage, IDL does not have a more reliable estimate of the total number of documents produced in the course of this MDL and related litigation matters.

no more than to give fodder to fruitless finger-pointing. Rather, *amici* view it as an indispensable element of any comprehensive strategy to ameliorate the country's ongoing drug use and overdose crisis and to prevent similar crises from occurring in the future. If history is any guide, the eventual benefits of the proposal outlined herein should well outweigh the comparatively low costs required for its implementation.

In the case of tobacco, the disclosure of documents that exposed the industry's duplicity likely played a greater role than any other litigation-related outcome in swaying public opinion on cigarette use. So long as smoking was regarded as a matter of personal choice, and smoking-related illness as the price one paid for one's own failings, public support for meaningful remedial action remained scant. As a clearer collective understanding of the forces that shaped individual choices to start or quit smoking began to form, however, so too did the collective will to pursue meaningful reform. Research has demonstrated that the policies enacted and resources mobilized as a result of changing public attitudes toward smoking have almost certainly done more for tobacco control than those enacted or mobilized by the MSA itself. Whereas serious concerns about the benefits of MSA payouts to the states emerged soon after the settlement's signing, the significance of the tobacco industry documents for national tobacco control efforts has become more obvious with each passing year.¹⁸ The lesson for the present case is clear: litigation can be an effective tool in addressing large-scale public health crises provided that it succeeds in preserving its original function as a public fact-finding process.¹⁹

¹⁸ The impact of the MSA's final provisions on public health are discussed in a prior amicus brief filed in this MDL: *Brief of Amici Curiae in Support of Settlement with Favorable Public Health Outcomes* Filed by Northeastern University Center for Health Policy and Law, In re: Nat'l Prescription Opiate Litig., MDL No. 2804 (May 9, 2019), Doc #: 1626, at 7-10. On the effects of the release of secret tobacco documents on public attitudes toward smoking and smoking-related illness, see BRANDT, *supra* note 2, at 437-440.

¹⁹ See, e.g., ELIZABETH C. BURCH, *MASS TORT DEALS: BACKROOM BARGAINING IN MULTIDISTRICT LITIGATION* (2019); Jennifer D. Oliva, *Opioid Multidistrict Litigation Secrecy*, 80 OHIO ST. L. J. __ (forthcoming 2019), available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3411746.

In sum, a resolution of the above-captioned litigation has a unique opportunity to make the public record on the opioid crisis as extensive and accessible as it has become in the case of tobacco. The defendants' financial resources are finite, but their internal documents too constitute valuable assets in the task ahead, for they can help shape public knowledge of the crisis in ways that are likely to make a lasting difference in the nation's response to it. The proposal put forward in this brief is well within the purview of any global settlement likely under consideration in the instant proceedings, more so certainly than of any individual trial court. By the same token, a global settlement also offers the defendants a unique opportunity to recover exclusive possession of these documents and shield them durably from public scrutiny. *Amici* urge the Court not to let this happen. These documents should see the light of day; the public's interest in their release is overwhelming.

Respectfully submitted,

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APPENDIX

An Estimate of Costs to Establish and Maintain an Opioid Documents Archive

By the UCSF Industry Documents Library



University of California
San Francisco

Library

530 Parnassus Avenue
Box 0840
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UCSF Industry Documents Library

Estimate of Costs to Establish and Maintain an Opioid Documents Archive

Background

The UCSF Industry Documents Library (IDL) seeks to preserve documents produced through opioid litigation and to make them freely available online for the public good.

Housed at the University of California, San Francisco, the IDL has been committed to the preservation and public accessibility of internal industry documents for 20 years. IDL's mission is to identify, collect, curate, preserve, and make freely accessible internal documents created by industries and their partners which have an impact on public health, for the benefit and use of researchers, clinicians, educators, students, policymakers, media, and the general public at UCSF and internationally. The IDL currently houses over 14 million industry documents which were released as a result of litigation against the tobacco industry and from other sources. The collections are publicly available to all at <https://industrydocuments.ucsf.edu>.

Opioid Documents Archive

The number of opioid documents which could become available through public disclosure in current litigation has been estimated as 7 million documents, or approximately 28 million pages. To establish and maintain a publicly accessible archive of this size in perpetuity, IDL proposes to use the same model which created the Truth Tobacco Industry Documents collection in 2002.

The Truth Tobacco Industry Documents Model

At the time of its founding, the Truth Tobacco Industry Documents collection (originally known as the Legacy Tobacco Documents Library) contained approximately 24 million pages. To build the archive, the UCSF Library hired a team of seven librarians and programmers to design and develop the infrastructure and user interface required to manage, preserve, and provide public access to the documents. Based on our experience, a similar level of effort would be needed to establish and maintain an opioid documents collection. Since its launch in 2001 the IDL has expanded to encompass more than 90 million pages. Besides tobacco, it now includes smaller sets of materials from drug, chemical, food and fossil fuel industries, and continues to grow.

A significant difference between the tobacco and opioid collections is that the tobacco documents were indexed prior to their acquisition by the UCSF Library, and included document-level metadata such as Title, Author, Document Date, and Organizations Mentioned. It is our understanding that such document-level metadata for the opioid documents has not yet been created, necessitating additional work to index the documents for fielded searching and maximum accessibility.

Academic Research Center

The UCSF Center for Tobacco Control Research and Education (CTCRE) was created alongside the Industry Documents Library to facilitate research, education, and training



related to the documents and to tobacco control generally. The co-development of a research center in parallel with IDL has proven to be a critical factor in ensuring that documents are shared with a wide audience beyond UCSF. Research by CTCRE faculty and students has been one of the most successful methods of raising awareness of the tobacco documents among academic, scientific, government, and public communities, and in interpreting findings into concrete policy changes and real improvements in public health.

UCSF faculty who are deeply involved in researching the opioid crisis have similarly committed their support to a digital library and research center focused on the opioid documents:

Daniel Ciccarone, MD, MPH, is the Principal Investigator of the Heroin in Transition study, funded by the National Institutes of Health (NIH) /National Institute on Drug Abuse (NIDA). This public health study investigates the “Triple Wave Epidemic” by examining the intersection between opioid pill, heroin and synthetic opioid (ie fentanyl) waves. This is a multidisciplinary, multi-level study incorporating the disciplines of public health, addiction medicine, economics, anthropology and statistical modeling. The team has published 23 peer-reviewed papers exploring the size and scope of the opioid crisis, user perspectives, supply and demand forces driving the epidemic and strategies for intervention, among others, and their work has received significant media attention.

Kelly Ray Knight, PhD, is Associate Professor in the Department of Anthropology, History and Social Medicine at UCSF. Her research has focused on the study of individual, interpersonal and socio-structural factors that contribute to health outcomes and healthcare utilization for people who use illicit substances. Dr. Knight is currently Principal Investigator (PI) of a NIDA-funded ethnographic study, Examining the Consequences of Reductions in Opioid Prescribing on Patients, Clinical Care, and Community Health, that seeks to improve understanding of the positive and negative consequences of reductions in opioid prescribing to inform clinical and policy recommendations. She served as PI of the completed NIDA-funded ethnographic study, Pain Management in the Clinic and Community which examined chronic, non-cancer pain management practices of primary care clinicians and their patients with a history of substance use in safety net clinical health care settings and patients’ home environments. She is also co-investigator on the NIDA-funded epidemiologic cohort study, Cohort Study of Opioids, Pain, and Safety in an era of Changing Policy. In 2017, Dr. Knight was appointed to the University of California Opioid Curriculum Taskforce to develop recommendations and curricula in response to the opioid crisis for implementation across all University of California medical schools.

Funding Requirements

To establish the Truth Tobacco Industry Documents archive and its companion Academic Research Center, the UCSF Library received a \$12.5 million gift from the American Legacy Foundation in 2001. The gift comprised a \$2.5 million fund for initial expenses including staffing and infrastructure costs, and a \$10 million fund to serve as an endowment to support maintenance and preservation of the collections in perpetuity.

Adjusting for inflation, a larger collection of documents, and the additional costs of indexing, the UCSF Library seeks a gift of \$30 million to establish an opioid documents archive, including \$5 million for initial expenses and \$25 million for an endowment fund.

Impact of Public Access to Industry Documents

When the Legacy Tobacco Documents Library was launched in 2002, it provided the first opportunity for public health researchers, lawyers, journalists, community advocates, and people adversely affected by tobacco and smoking to access these previously-secret documents and to determine the truth about the tobacco industry's activities and tactics. Opening these documents to the public proved critical in understanding the impact the industry had on the rise of smoking, the increase in tobacco-related diseases and deaths, scientific research and study, and the public health burden placed on communities and healthcare systems.

Hosting the documents in one central library database meant that researchers could access any of the documents, at any time, from anywhere in the world, enabling a surge of study and analysis which has been supported by dozens of national research grants and which has produced over 1,000 publications. These include peer-reviewed academic studies, monographs, news articles, documentaries, and major public health reports by the World Health Organization and other civil society organizations. The documents have also been used extensively in litigation against the tobacco industry around the world; in parliamentary and legislative hearings; and have informed tobacco control policy work and regulations throughout the U.S. and globally.

To maximize the public benefit of opioid litigation efforts, it is imperative that these discovery documents be made publicly and freely available. The UCSF Industry Documents Library has served as a permanent and stable repository for industry documents since 2002 and is fully committed to providing access to documents which present the truth about industry's impact on public health. Preserving opioid litigation documents for public research and investigation will shed light on industry practices and shape the social and political environment of opioid manufacture and distribution for generations to come.